UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,105	09/10/2004	Takayuki Fujii	Q83547	2105

23373 7590 08/29/2005

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
MARTIN, PAUL C	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/507,105	FUJII, TAKAYUKI	
	Examiner	Art Unit	
	Paul C. Martin	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

DETAILED ACTION

Specification

The abstract of the disclosure is objected to because it contains more than one paragraph. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by the inventor.

The courts have stated:

"To fulfill the written description requirement, a patent specification must clearly describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention with all its claimed limitations, no that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F3d at 1572, 41 USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

It is deemed that Applicants were not in possession of the entire scope of the claims at the time the invention was made. Although Applicant has described a limited number of substances having an activity of inhibiting lactate dehydrogenase activity, Applicant has not provided a representative sample of each substance in order to substantiate the contention that Applicant was in possession of all permutations of every known lactate dehydrogenase activity inhibitor.

Even a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

It is known that there are numerous lactate dehydrogenase activity inhibitors that are not even mentioned in the Instant specification. Thus, it is deemed that Applicants were not in possession of the full scope of the claimed invention. The reason that claims 1-7 and 10 are rejected under this statute is because there is no one claim which states any combination which was clearly possessed by Applicants at the time the invention was made.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 6 and 7, the phrase "may contain" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Madappally et al. (4,241,179)

Madappally et al. teaches a two reagent system for measuring the activity of glutamate pyruvate transaminase, also known as alanine aminotransferase. The first reagent contained at least nicotinamide adenine dinucleotide, lactate dehydrogenase, and L-alanine. (Column 6, Table 1) The second reagent contained at least, a substance having an activity of inhibiting lactate dehydrogenase activity i.e., oxalic and oxamic acid or salts thereof, and alpha-ketoglutarate, also known as 2-oxoglutaric acid. (Column 6, Table 2)

Madappally et al. teaches a method for measuring the activity of alanine aminotransferase by bringing a sample to by analyzed into contact with L-alanine, 2-oxoglutaric acid, lactate dehydrogenase in a final concentration of 200-500 U/L , nicotinamide adenine dinucleotide, and substances having an activity of inhibiting lactate dehydrogenase activity i.e., oxamic and oxalic acid, (Column 4, Lines 62-68, Column 5, Lines 1-8, Column 6 Table 1) and measuring the increased/decreased amount of oxidized/reduced nicotinamide adenine dinucleotide generated. (Column 1, Lines 45-55)

Wherein claim 3 recites "same reagent-component", this phrase is not specifically defined in the specification. Therefore, it is given its broadest possible interpretation, within reason, in terms of examination. It is deemed that because all of the components were combined with the sample, that this combination taught by Madappally et al of: sample, lactate dehydrogenase, lactate dehydrogenase inhibitor, L-alanine, 2-oxoglutaric acid, and oxidized nicotinamide adenine dinucleotide anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madappally et al.

Madappally et al. teaches a two reagent system for measuring the activity of glutamate pyruvate transaminase, also known as alanine aminotransferase. The first reagent contained at least nicotinamide adenine dinucleotide, lactate dehydrogenase, and L-alanine. The second reagent contained at least, a substance having an activity of inhibiting lactate dehydrogenase activity; oxalic and oxamic acid or salts thereof, and alpha-ketoglutarate, also known as 2-oxoglutaric acid. (Column 4, Lines 62-68, Column 5, Lines 1-8)

Madappally et al. teaches a method for measuring the activity of alanine aminotransferase by bringing a sample to by analyzed into contact with L-alanine, 2-oxoglutaric acid, lactate dehydrogenase in a final concentration of 200-500 U/L , nicotinamide adenine dinucleotide, and substances having an activity of inhibiting lactate dehydrogenase activity; oxamic and oxalic acid. (Column 4, Lines 62-68, Column 5, Lines 1-8, Column 6 Table 1)

Madappally does not teach the use of a concentration of oxamic acid or salt thereof, from 0.005 to 5 mmol/L as a final concentration in a measuring system.

One of ordinary skill in the art would have been motivated to use the following ratios because the artisan would have recognized that these proportions were conventional in the art at the time and that the artisan would have had a reasonable expectation of success using these ratios.

Madappally et al. teaches the use of a concentration of oxamic acid at 10-30mmol/L per 200-500U/L of lactate dehydrogenase. Applicants' claims call for use of a concentration of oxamic acid (or salt thereof) at 0.005 to 5mmol/L per 100U/L or more of lactate dehydrogenase. On average, applicants' ratio of oxamic acid to lactate dehydrogenase is about 1:20. Madappally et al. teach an average ratio of oxamic acid to lactate dehydrogenase of about 1:17.5.

The MPEP states that: "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)" as well as "[A] prior art reference that discloses a range encompassing a somewhat narrower claimed range is sufficient to establish a prima facie case of obviousness." In re Peterson, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382-83 (Fed. Cir. 2003)".

Variations among the concentrations concerning enzymatic assays are conventional in the art. It is noted, as stated above, that the ratios disclosed by Madappally et al. is a narrower range that is very close to the claimed range. Optimization of variables is considered routine experimentation, well within the purview of the ordinary artisan at the time of the invention.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence or evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin
Examiner
Art Unit 1655

8/22/05

PATRICIA LEITH
PRIMARY EXAMINER